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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,489	01/23/2001	Lisa Joanne Drewe	41577/252464	5644

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JOHN S. PRATT, ESQ  
KILPATRICK STOCKTON, LLP  
1100 PEACHTREE STREET  
ATLANTA, GA 30309

EXAMINER
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CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

MAIL DATE	DELIVERY MODE
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10/16/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

### Application No.

09/744,489

### Applicant(s)

DREWE ET AL.

### Examiner

Suryaprabha Chunduru

### Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,6,8-12,18,19 and 22-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,6,8-12,18,19 and 22-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

1. Upon considering the pre-appeal decision, the finality of previous office action is withdrawn and this Non-Final action is made to address the issues raised in the pre-appeal brief.

***Status of the Application***

2. Currently claims 1-2, 5-6, 8-12, 18-19, 22-26 are pending. Claims 1, 18, 25 are amended. Claims 3-4, 7, 13-17, 20-21 are cancelled. Applicants' arguments are fully considered and found persuasive for the reasons that follow.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5-6, 8, 12, 22, 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Orum et al. (Nucleic Acids Res., Vol. 21, No. 23, page 5332-5336, 1993).

Note: The instant specification discloses a 'purine-rich region' means that the sequence is suitable for strand invasion by peptide nucleic acid (PNA). Such regions suitably contain at least four consecutive purine residues. Accordingly the following rejection is based on primers comprising at least four consecutive pyrimidine residues on 5' end of the primers, which during amplification introduce purine-rich region into the target nucleic acid suitable for PNA binding and triplex structures are formed between double-stranded target DNA and PNA probe.

Orum et al. teach a method of claim 1, 6, for detecting the presence of a target nucleic acid sequence in a sample, said method comprising

(a) amplifying said target nucleic acid and introducing a purine rich-region into the target sequence during amplification (which results in amplification product that includes purine-rich region (see page 5333, col. 1, paragraph 1-2, the primers indicate at least four consecutive pyrimidine residues which are introduced into the target); and contacting the sample during the amplification with a peptide nucleic acid that binds at least a portion of the target sequence (see page 5333, Fig. 1-2, col. 1, paragraph 2-3, paragraph 1 under results section, col. 2, paragraph 1-2);

(b) detecting the presence of triplex structure (PNA/DNA hybrid) from the binding of the amplified target sequence to the PNA , wherein the detection of the presence of triplex structures indicates the presence of target nucleic acid in the sample (see page 5333, col. 2, paragraph 1, Fig. 2, page 5334, Fig. 3, page 5335, Fig.7).

With regard to claim 2, Orum et al. teach that the PNA is bis-PNA (see page 5335, Fig. 7 indicating the use of two PNAs).

With regard to claim 5, 22, Orum et al. teach that the amplification is a polymerase chain reaction (see page 5333, col. 1, paragraph 2).

With regard to claim 8, Orum et al. teach that the primers used in the amplification comprise plurality of pyrimidines at the 5' end thereof (see page 5333, col. 1, paragraph 1).

With regard to claim 12, 24, Orum et al. teach that the triplex structure is detected by gel retardation method (see page 5333, col. 2, paragraph 1, Fig. 2, page 5334, Fig. 3, page 5335, Fig.7). Accordingly the instant claims are anticipated.

*Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9-11, 18-19, 23, 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orum et al. (Nucleic Acids Res., Vol. 21, No. 23, page 5332-5336, 1993) in view of Graham et al. (WO 97/05280).

Orum et al. teach a method for detecting the presence of a target nucleic acid in a sample as discussed above in section 3.

However, Orum et al. did not teach use of a solid support, a surface plasmon resonance detector and a kit.

Graham et al. teach a method for detecting the presence of a target nucleic acid wherein Graham et al. teach a method comprises surface enhanced Raman scattering techniques for

detecting target nucleic acids (see page 10, line 1-34). Graham et al. teach that the method comprises hybridizing target with SERS- active surface, which is in the form of a coating on a waveguide (see page 23, line 8-32). Graham et al. teach a kit for detecting a target nucleic acid in a sample, wherein the kit comprises a peptide nucleic probe sequence which is immobilized on a waveguide of an evanescent wave detector apparatus (see page 57, line 6-35, page 58, line 1-22, page 14, line 13-16, page 47, line 1-3, page 49, line 13-35, page 50, line 1-12), and a set of primers (see page 58, line 9-16 indicates a kit comprises other reagents for manipulating target nucleic acids, page 62, line 21-25, page 82, line 18-35, page 83, line 1-35, page 84, 1-12 indicating that the kit comprising other reagents include primers).

With regard to claim 26, Graham et al. teach that the kit evanescent wave detector apparatus, that is a surface plasmon resonance detector (see page 14, line 13-16, page 47, line 1-3, page 49, line 13-35, page 50, line 1-12).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method for detecting the presence of a target nucleic acid in a sample as disclosed by Orum et al. with a step of using a solid support, a waveguide detector as taught by Graham et al. for the purpose of developing a sensitive detection method for detecting a target nucleic acid. One skilled in the art would be motivated to combine the method as disclosed by Orum et al. in a manner taught by Graham et al. by the inclusion of a step of using a waveguide detector because Graham et al. explicitly taught that the use of the waveguide detector provides an increased sensitivity in detecting low copy number target nucleic acids in a sample and potentially be a quick and cost-effective method for detecting target nucleic acids in a sample, wherein the combined effect of surface enhancement and the resonance effect result in

increases in sensitivity and robustness (see page 4, line 35, page 5, line 1-14, page 11, line 5-34).

An ordinary artisan would have a reasonable expectation of success that inclusion of the waveguide detector for detection of the target nucleic acid would result in improving the sensitivity, robustness and cost-effective method for detecting the target nucleic acids as suggested by Graham et al. and such modification of the method would be obvious over the cited prior art.

Further it is obvious to combine the components of the method taught by Orum et al. in to a kit format as taught by Graham et al. to achieve expected advantage of developing a ready to use sensitive kit for detecting a target nucleic acid because one of the ordinary skill in the art would have a reasonable expectation of success that the combination would result in cost-effective ready to use kit because Graham et al. explicitly taught a ready-to use kit comprising PNA immobilized on a surface plasmon resonance detector (page 14, line 13-16, page 47, line 1-3, page 49, line 13-35, page 50, line 1-12) and such a modification of the method is obvious over the cited prior art.

***Response to arguments:***

5. With regard to the rejection of Claims 6, 22-24 under 35 U.S.C. 103(a) as being unpatentable over Vary et al. in view of Egholm et al. Applicants' arguments are fully considered and found persuasive. The rejection is withdrawn herein.

6. With regard to the rejection of Claims 1, 2, 5, 8-9, 12 under 35 U.S.C. 103(a) as being unpatentable over Vary et al. in view of Egholm et al. and Livak et al., Applicants' arguments are fully considered and found persuasive. The rejection is withdrawn herein.

7. With regard to the rejection of claims 25-26 under 35 U.S.C. 103(a) as being unpatentable over Graham et al. in view of Egholm et al., Applicants' arguments and amendment are fully considered and found persuasive. The rejection is withdrawn.

8. With regard to the rejection of claims 10-11, 18-19 under 35 USC 103(a) as being unpatentable over Vary et al. in view of Egholm et al. and Livak et al. further in view of Graham et al., Applicants' arguments and amendment are fully considered and found persuasive. The rejection is withdrawn.

### ***Conclusion***

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru  
Primary Examiner, Art Unit 1637

*Suryaprabha Chunduru* 9/29/07  
SURYAPRABHA CHUNDURU  
PRIMARY EXAMINER